NOVARTIS

Production Manager

Job ID
REQ-10025567
Oct 11, 2024
USA

About the Role

Key Responsibilities:

Responsibilities include but not are limited to:

- Responsible for the daily operations and efficient utilization of resources to meet processing demands.
- Ensure the products are produced, inspected, stored and released in accordance with approved procedures. Establish and maintain Production unit in full GMP and HSE compliance
- Support shop floor trouble shooting and problem solving as needed.
- Responsible for authoring, reviewing and/or approving GMP documents including but not limited to SOPs, Batch Records, Labels, Protocols, Reports, Validation documents.
- Ensure Good Documentation Practice are followed on the shop floor.
- Ensure production team receives complete cGMP training and are qualified to perform the required operations.
- Support compliance activities including deviations, CAPAs, Investigation and OOS and OOT
- Interview and hire production staff in conjunction with other functions and/or Head of Production.
- Implement cost control programs or procedures.
- Audit and review emergency paperwork and processes to ensure compliance.
- Monitor and regulate staffing needs to ensure optimum staffing levels are supporting business demands.

- Establish and optimize training programs for manufacturing.
- Assist in preparation for commercial launch, including commissioning and qualification of rooms and equipment.
- Ensure and maintain qualified status of production equipment and methods for intended use in Production lines; Ensure adequate management of Production related validations, transfers, investigations related activities (deviations, OOS, OOE, OOT, CAPAs, trending), and Change Control systems.
- Prepare for and participate in Health Authority inspections and internal audits; Ensure Production personnel are duly qualified, and manufacturing is properly conducted and documented for all performed activities; Evaluate and approve Production records as required and manage the staff objectives, performance, and development.
- Analyze Key Performance Indicators with a statistical mindset to identify opportunities for improvement.
- Collaborate with supply chain organization to plan production and deliver 100% On-Time-In-Full deliveries.
- Perform analysis of trends in deviations and other events and facilitate resolution defining action plans.
- Follow-up on actions to ensure timely execution; Help promote an unbossed culture supporting ownership, innovation, speak-up, and accountability.

Job Dimensions:

Number of associates:

Direct: 3-5 associates

Financial responsibility:

(Budget, cost, sales, etc.)

Manufacturing OPEX budgets.

Responsible for drug product COGS >US $1 million.

Working Conditions:

- Ensures reliable and compliant operations. Improves outcome in regulatory inspections.
- On-site with daily presence in a pharmaceutical laboratory and manufacturing facility.

Essential Requirements:

- BS degree in life sciences, engineering, chemistry, biotechnology, or related field or equivalent relevant experience
- Training in radiochemistry or radio pharmacy is an preferred
- 4 or more years' experience in GMP operational roles with direct experience in pharmaceutical manufacturing, specifically low bioburden manufacturing preferred, 3+ years of leadership experience.
- Involvement with quality regulatory inspections of facilities from major agencies such as FDA or EMA.
- Shows the appropriate sense of urgency around given tasks
- Strong change management skills, adaptability, and the ability to work under pressure.
- Proficient technical writing skills.
- Proven ability to plan and manage operational process for maximum efficiency and
- Good understanding of manufacturing and validation requirements and activities.
- Radiation safety education (desired).
- Strong leadership skills (communication, cross-functional teamwork, drive to enable problem solving).
- Leverage new technologies and techniques to eliminate non-value adding activities and improve productivity / performance through new processes.

Commitment to Diversity & Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve

Role Requirements

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Operations
Business Unit
Innovative Medicines
Location
USA
Site
Carlsbad
Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Production Manager

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